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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,474	03/13/2001	Gennady V. Merkulov	CL000891	8769

25748 7590 11/15/2004

CELERA GENOMICS CORP.
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ROCKVILLE, MD 20850

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/804,474	Applicant(s) MERKULOV ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,8,9 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,8,9 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claim 24 has been amended and claims 1-3, 6-7, and 12-21 have been cancelled as requested in the amendment filed on September 23, 2004. Claims 4, 8, 9 and 24-29 are pending in the instant application.

Claims 4, 8, 9 and 24-29 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on March 08, 2004 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Specification

5. Claim 4 remains not in compliance with the requirements for Sequence Identifiers (see MPEP 2422.03) for those reasons of record in section 5 of Paper mailed on October 06, 2003.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

6. Claims 4, 8, 9 and 24-29 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record as applied to claims 4, 9 and 24-26 in section 7 of Paper mailed on

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October 06, 2003. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

Applicant traverses the rejection on the premises that the claimed isolated nucleic acid molecules have several uses (middle at page 8 of the Response) such as encoding “the protein of the present invention as transporter family” (bottom at page 8). Applicant further submits that “[t]he disclosure of the function of the transporter is sufficient. Such function is quite specific for transporter proteins and differentiates them from other proteins. As such, this function is specific enough to define a use for novel transporter proteins and transporter-encoding nucleic acid molecules in the drug discovery process” (top at page 10 of the Response). These arguments have been fully considered but are not deemed to be persuasive for the following reasons.

The assertion that the instant claimed isolated nucleic acid molecules encode a protein, which belongs to a transporter family of proteins, has been never disputed by the Examiner. The importance of transporter proteins in cellular physiology is well established in the art. However, the issue at hand remains that the instant specification, as filed, fails to identify a specific biological role for this particular novel transporter protein encoded by the claimed nucleic acid molecules or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect. In the absence of such critical information, Applicant’s invention is incomplete because it is a matter of law that the claimed invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention. The fact that Applicant submits that “[n]ovel transporter

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proteins/nucleic acids are commercially useful for developing therapeutic/diagnostics for these and other pathologies” (top at page 10) without identifying any specific “pathologies” simply confirms that the instant invention was not completed as filed, and, therefore, clearly lacks utility in currently available form.

Applicant further argues that “isolated nucleic acid molecules that encode a transporter protein (SEQ ID NO: 2), has useful value in the drug discovery process even though the molecule may not be associated with a specific treatment and/or diagnosis of a particular disease” and refers to *Nelson v. Bowler* (top at page 9 of the Response). This argument has been considered but is not persuasive for the following reasons. In *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881 (CCPA 1980), the court reversed a finding by the Office that the applicant had not set forth a “practical” utility under 35 U.S.C. 101. In this case the applicant asserted that the composition was “useful” in a particular pharmaceutical application and provided evidence to support that assertion. Courts have used the labels “practical utility,” “substantial utility,” or “specific utility” to refer to this aspect of the “useful invention” requirement of 35 U.S.C. 101. The Court of Customs and Patent Appeals has stated:

Practical utility is a shorthand way of attributing “real-world” value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner, which provides some immediate benefit to the public, emphasis added. In the instant case, there appears to be no assertion of even one specific, substantial and credible utility presented in the instant specification, as filed, or specifically articulated in Applicant’s Response, that would indicate that public would immediately benefit from the disclosure of the instant claimed nucleic acid molecules.

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Applicant refers to *Juicy Whip v. Orange Bang* (Fed. Cir. 1999), which held that in order to violate the utility requirement, an invention must be “totally incapable of achieving a useful result”. Applicant submits that “[t]he polypeptides and encoding nucleic acid molecules of the present invention are well known in the art to be valuable drug targets and therefore have readily apparent commercial utilities, such as for screening potential drug compounds, producing antibodies, developing hybridization probes and primers, etc.” (page 9, last paragraph of the Response). Again, this argument is not deemed to be persuasive because, as fully explained in the previous office action of record, to employ a nucleic acid of the instant invention in screening for potential drug compounds without any knowledge of a particular disease or pathological condition, that could be treated if such compound was identified in a proposed “screening method”, would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability. Furthermore, to employ the DNA of the instant invention as “probes, primers, chemical intermediates, and in biological assays” (page 42, last paragraph) is not a “real world” utility because it would eventually relate to a protein for which no biological function is known.

Thus, because the instant specification does not disclose a credible “real world” use for the claimed polynucleotides in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

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Claim Rejections - 35 USC § 112

7. Claims 4, 8, 9 and 24-29 are also rejected under 35 U.S.C. 112, first paragraph for reasons of record as applied to claims 4, 9 and 24-26 in section 8 of Paper mailed on October 06, 2003.

Conclusion

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

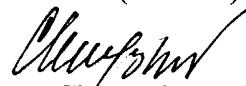
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Olga N. Chernyshev, Ph.D.
Primary Examiner
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